K123885

510(k) Summary

JUN 0 3 2013

Submitter Information:

OsteoMed
3885 Arapaho Road
Addison, Texas 75001
Phone: (972) 677-4600
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Contact Person: Mrs. Piedad Peña

Date Prepared: May 15, 2013

Device Information:

Proprietary/Trade Name: OsteoMed smartflex Cranial Spring Distraction System
Common Name: Cranial Spring Distractor
Classification Name:

- Regulation Number: 21 CFR 882.5330
- Regulation Name: Preformed nonalterable cranioplasty plate
- Product Code: PBJ

Device Class: II

Predicate Devices:

OsteoMed Cranial Distraction System, K121304

- Classification Name: Regulation Number: 21 CFR 882.5330
- Regulation Name: Preformed nonalterable cranioplasty plate
- Product Code: PBJ

Device Class: II

KLS – Martin, Molina Orbital Malar Distractor, K003883

- Classification Name: Regulation Number: 21 CFR 872.4760
- Regulation Name: Bone Plate
- Product Code: JEY

Device Class: II

OsteoMed External Mandibular Distraction System, K063792

- Classification Name: Regulation Number: 872.4760
- Regulation Name: Bone Plate
- Product Code: MQN

Device Class: II

Device Description:

The OsteoMed smartflex Cranial Spring Distraction System is a distraction osteogenesis system consisting of distractors in various sizes. The distractor is anchored to the cranium by the distractor foot plate. The distractor gradually distracts the bone segments by applying a continuous force to the bones of the skull facilitating remodeling to expand the prematurely closed suture. The distractors are removed after consolidation.

The instruments used with the system are pliers, benders, plate cutters and other instruments to facilitate the placement and removal of the OsteoMed smartflex cranial spring distractors.

The OsteoMed smartflex Cranial Spring Distractors are made from Medical Grade Stainless Steel per ASTM F-138.

Indications For Use/Intended Use:

The OsteoMed smartflex Cranial Spring Distraction System is intended for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial bones. This device is intended to be removed after consolidation. The OsteoMed smartflex Cranial Spring Distraction System is intended for single patient use only.

Intended use is equivalent to the OsteoMed Cranial Distraction System and the KLS-Martin predicate devices.

Target Population:

Pediatrics; Sub-population – Infant greater than 1 month to 2 years of age

Technological Characteristics:

The OsteoMed and KLS predicate devices are internal distractors for bone elongation, which distracts manually via a threaded rod and are anchored using bone screws. The KLS distractor predicate has hook feet which anchor to the cranial bone edge and uses bone screws to anchor to the cranial bone. The OsteoMed smartflex Cranial Spring Distractor is also an internal distractor for bone elongation as the predicate devices, but it distracts via continuous spring force and is anchored by hook feet to the cranial bone edge.

Material used for the OsteoMed smartflex Cranial Spring Distractor is medical grade stainless steel. The material used for the OsteoMed External Mandibular Distraction System (K063792) implantable K-wires, which are implanted during distraction, are medical grade stainless steel. The stainless steel material used in the OsteoMed smartflex Cranial Spring Distractor and the OsteoMed Implantable K-wire is biocompatible.

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Performance / Clinical Data:

The OsteoMed smartflex Cranial Spring Distraction System was compared to the distraction rates and verified forces of the OsteoMed Cranial Distraction System. Verification testing consisted of the following tests;

- Finite Element Analysis of Forces Applied to Adjacent bone simulating infant skull properties for the Cranial Vault Distractor Predicate and the OsteoMed SmartFlex Cranial Spring Distractor were created. The results show that both devices exerted a stress on the cranial bone below the yield strength of infant cranial bone. The stress on the cranial bone for the Cranial Spring Distractor was 80% below the stress on the cranial bone of the Cranial Distractor (predicate).
- Distraction distance was evaluated graphically using clinical data obtained by surgeons with cranial spring devices similar to our device. The data included 91 clinical cases performed on infants ranging in age from 3 – 8.5 months with cranial springs manufactured by a physician in cranial distraction, 31 cases reached 55mm of distraction and 60 cases went safely beyond 55mm with only one clinical complication, a skin infection and 3 spring related complications (repositioning of the springs). The maximum possible distraction distance of the OsteoMed Cranial Spring Distractor is 55mm because that is the maximum length at free state that does not compromise patient safety.
- Distraction rate was obtained from the clinical data and distraction rates compared to the predicate. The distraction rate on average with a six week duration was 1.39mm per day.
- The OsteoMed smartflex Cranial Spring Device design was verified to prove the spring geometry and force targets were met as described in the literature. Spring geometry was verified using an optical comparator and the implants were compressed between the footplates to simulate initial force at implantation, where the force was measured.

The indications for use of the OsteoMed smartflex Cranial Spring Distraction System are the same as the OsteoMed Cranial Distraction System (K121304) and KLS-Martin Molina Distraction System (K003883) predicate devices.

Clinical Testing is not required to support substantial equivalence.

In conclusion, the device is safe and effective and performs as well as the OsteoMed Cranial Distraction System and the KLS-Martin predicate devices.

Substantial Equivalence:

Substantial equivalence for this device is based on similarities in intended use, indications for use, function, performance, and operational principle to the predicate devices, OsteoMed Cranial Distraction System (K121304) and KLS-Martin Molina Distraction System (K003883), based on their promotional materials, labeling and clearance letters. The basis for substantial equivalence for this device is also on similarities in materials with the OsteoMed External Mandibular Distraction System (K063792) implantable Stainless Steel K-wires base on their promotional materials, labeling and clearance letters. The system is provided sterile based on the predicate device (K922211) Sterilization Testing.

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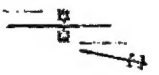
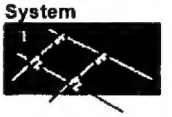
System/ MFG Device	OsteoMed Smartflex Cranial Spring Distractor 	OsteoMed Cranial Distraction System 	KLS-Martin Molina Orbital Malar Distractor 	OsteoMed External Mandibular Distraction System 	OsteoMed ReFlexion Toe Implant System
510 (k)	(New)	K121304	K003883	K063792	K922211
Purpose		(Predicate)	(Predicate)	(Predicate – Material implant)	(Predicate – Gamma Sterilization)
Product Code/ Classification	PBJ 21CFR882.5330	PBJ 21CFR882.5330	JEY, 21CFR 872.4760	JEY 21CFR 872.4760	LZJ, Unclassifed
Intended use:	Cranial conditions	Cranial conditions	Cranial and Midface Conditions	External distraction of Mandible Conditions	reconstruction of the 1st MTP, resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis or revision of previous arthroplasty
Indications for use:	Intended for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial bones. This device is intended to be removed after consolidation.	Intended for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial bones. This device is intended to be removed after consolidation.	KLS-Martin Molina Orbital Malar Distractor is intended for use in the treatment of cranial and midface conditions such as syndromic craniosynostosis and congenital midface deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial and midface bones.	The OsteoMed External Mandibular Distraction System, which is a family of external distraction osteogenesis devices for bone elongation for the correction of congenital deficiencies, mandibular hypoplasia or post traumatic defects of the mandible that require gradual distraction. The OsteoMed External Mandibular Distraction System is intended for use in either adults or pediatric patients. The OsteoMed External Mandibular Distraction System is intended for single patient use only.	three-piece implant system designed for the reconstruction of the 1st MTP, resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis or revision of previous arthroplasty
Target population:	Pediatrics	Pediatrics	Pediatrics	Pediatrics and Adults	Adults
Anatomical sites:	Cranium	Cranium	Cranium and Midface	Mandible	1st MPJ (toe)
Function:	Distraction of cranial bones	Distraction of cranial bones	Distraction of cranial and midface bones.	Distraction of mandibular bones	Reconstruction of the 1st MPJ
Design:	Distraction via spring forces and Anchored by hooks on feet (feet plates)	Distraction force applied by surgeon/parent by activating the distraction rod. Anchored by Plate and Screws	Distraction force applied by surgeon/parent by activating the distraction rod. Anchored by Plate and Screws, and hooks on feet	Distraction force applied by surgeon/parent/patient by activating the distraction rod onto the K-wires. Anchored by K-Wires through the mandibular bone.	N/A
Maximum Distraction:	55mm*	25mm	35mm	70mm	N/A

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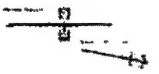
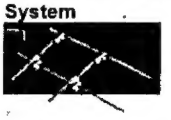
System/ MFG Device	OsteoMed Smartflex Cranial Spring Distractor 	OsteoMed Cranial Distraction System 	KLS-Martin Molina Orbital Malar Distractor 	OsteoMed External Mandibular Distraction System 	OsteoMed ReFlexion Toe Implant System
510 (k)	(New)	K121304	K003883	K063792	K922211
Distraction rate:	0.4mm per day	1mm per day (0.5mm twice a day)	1mm per day (0.5mm twice a day)	1mm per day (0.5mm twice a day)	N/A
Materials for Implants:	Distractor: Stainless Steel (316 SS LVM) ASTM F-138			Implantable K-Wires: Stainless Steel (316 SS LVM) ASTM F-138	Titanium Alloy, CoCrMo Alloy, UHMWPE
Bio-compatibility:	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Biocompatible
Sterility:	Provided Sterile (Gamma)	Provided non-sterile (Steam Sterilization by end user)	Provided non-sterile (Steam Sterilization by end user)	Provided non-sterile (Steam Sterilization by end user)	Provided Sterile (Gamma)
Techno-logical Char-acteristics:	Spring distractor	Distraction rod and tool for distraction	Distraction rod and tool for distraction	Distraction rod and tool for distraction	N/A
Operational Principle:	Distraction osteogenesis	Distraction osteogenesis	Distraction osteogenesis	Distraction osteogenesis	N/A

Due to the similarity of intended use, indications for use, function, materials, performance, and operational principle to the predicate devices, OsteoMed believes that the OsteoMed smartflex Cranial Spring Distraction System does not raise any new safety or effectiveness issues.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 3rd, 2013

OsteoMed
% Ms. Piedad Peña
Manager, Regulatory Affairs
3885 Arapaho Road
Addison, Texas 75001

Re: K123885
Trade/Device Name: OsteoMed smartflex Cranial Spring Distraction System
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PBJ
Dated: April 23, 2013
Received: April 24, 2013

Dear Ms. Peña:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Director of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123885

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Target Population:
Pediatrics; Sub-population – Infant greater than 1 month to 2 years of age

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123885